

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

INGENUS PHARMACEUTICALS, LLC and
LEIUTIS PHARMACEUTICALS LLP,

Plaintiffs,

v.

ACCORD HEALTHCARE INC.,

Defendant.

C.A. No. 23-0377-JLH

**STIPULATION AND [PROPOSED] ORDER REGARDING NONLIMITING
LANGUAGE OF THE PREAMBLE OF THE ASSERTED CLAIMS**

Plaintiffs Ingenus Pharmaceuticals, LLC And Leiutis Pharmaceuticals LLP (collectively, “Plaintiffs”) and Defendant Accord Healthcare, Inc. (“Accord”) hereby STIPULATE, and AGREE as follows:

WHEREAS the parties seek to conserve their own and the Court’s resources by narrowing the issues for trial in this case;

WHEREAS Claim 1 of the ‘952 Patent recites “a stable liquid parenteral formulation of cyclophosphamide;”

WHEREAS the parties wish to resolve any issues regarding the nonlimiting nature of the language of the preamble of the asserted claims;

IT IS HEREBY STIPULATED AND AGREED, by and among the parties for purposes of this litigation only, subject to the approval of the Court:

1. The language of the preamble of the asserted claims (i.e., a stable liquid parenteral formulation of cyclophosphamide) is not limiting.
2. Accord will not advance a non-infringement position based on the language of the preamble.

3. Ingenus will not argue or present evidence that the prior art does not meet the preamble as a limitation. That is, Ingenus will not argue that the asserted claims are valid because the prior art does not disclose “a stable liquid parenteral formulation of cyclophosphamide.”

4. The accused ANDA product is a “stable liquid parenteral formulation of cyclophosphamide.”

5. The accused ANDA products contain polyethylene glycol in an amount within the range of “about 3.4% to about 8.8% based on total formulation weight.”

6. The accused ANDA products contain propylene glycol in an amount within the range of “about 3.4% to about 4.4% based on total formulation weight.”

7. The accused ANDA products contain polyethylene glycol and propylene glycol in a mass ratio of approximately 1.0:1.0.

8. The accused ANDA products contain Monothioglycerol in a concentration of “about 0.01% to about 0.02%” based on total formulation weight.

Dated: February 20, 2025

SMITH, KATZENSTEIN &
JENKINS LLP

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IT IS SO ORDERED, this _____ day of February 2025.

The Hon. Jennifer L. Hall
United States District Court Judge